

REMARKS**I. Status of the Claims**

Claims 1-4, 6, and 20-25 are under examination. Claims 1 and 20 have been amended and claims 22-23 have been cancelled.

Claim 1 has been amended to recite “wherein the antibody promotes bone-forming activity in a mammal.” Claim 20 has been amended to recite that the antibody is generated using frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen. Support for these amendments may be found throughout the specification and in particular in original claim 1, and in paragraphs 12, 41-42, 47, and 103-106 of the published application (U.S. Patent Application No. 2008/0166356-A9).

No new matter has been added. Reconsideration of the claims in view of the present amendments and remarks is respectfully requested.

II. Amendments to the Specification

The first line of the specification was previously updated to reflect that Application Serial No. 10,169,545 is now U.S. Patent No. 7,098,372. (*See* U.S. Patent Application No. 2008/0166356-A9).

III. Claim Rejections**A. Maintained Rejections under 35 U.S.C. §112, first paragraph; Enablement**

Claims 20-24 remain rejected under 35 U.S.C. §112, first paragraph as allegedly lacking full enablement. In order to expedite prosecution of the present case, and without conceding the Examiner’s position or the validity of the rejection, Applicant has amended claim 20 to recite “at least one antibody generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen.” Claims 22-23 have been cancelled without prejudice or disclaimer.

The amended claims are fully enabled for generating an antibody using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen, including the specified

In order to expedite prosecution of the present case, and without conceding the Examiner's position or the validity of the rejection, claim 20 has been amended to recite "at least one antibody generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen and wherein the antibody is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1." Claims 22-23 have been cancelled. Claims 20 and 24 require that the pharmaceutical composition comprises an antibody that is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1.

As an initial matter, the SARP proteins described by Umansky are not identical to the sFRP-1 protein of SEQ ID NO:2. Thus, it follows that antibodies generated using Umansky's protein or fragments thereof, will be different from the claimed antibodies. Therefore, Umansky cannot anticipate antibodies generated using an sFRP-1 protein of SEQ ID NO:2 as an immunogen. The claimed compositions and the antibodies of Umansky are not identical as concluded by the Examiner. It is noted that even though there is a region of identity between Umansky's SARP protein and SEQ ID NO:2 (i.e., amino acids 217-231) claim 24 requires that the antibody is generated using at least this fragment as an immunogen and is also capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1. Thus, since claims 20 and 24 require the use of a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen, Umansky cannot anticipate the pending claims.

Furthermore, Umansky provides no teaching or suggestion with regard to the unexpected property of the claimed pharmaceutical compositions comprising the claimed antibodies for regulating bone-forming activity in a mammal. Finally, Umansky does not teach an antibody with the property that it is capable of inhibiting cell death mediated by overexpression of the polynucleotide set forth in SEQ ID NO:1.

In view of the remarks and amendments provided herein, Umansky fails to anticipate pending claims 20-21, and 24.

The rejection of claims 20-24 under 35 U.S.C. §102(e) as allegedly being anticipated by Rubin et al. (U.S. Patent No. 6,479,255) ("Rubin") has been maintained. The Examiner states that

to SEQ ID NO:2 of the instant invention. The Examiner states that even though the polynucleotide sequences are not identical, the expression product is identical. The Examiner concludes that even though Rubin does not expressly teach that the FRP antibody is capable of inhibiting cell death mediated by overexpression of sFRP-1 gene, and the use of the composition for regulating bone-forming activity, that these activities would be considered inherent in the composition since it has exactly the same components recited in the claims. The Examiner further states that the preamble phrase “for regulating bone-forming activity” is not given patentable weight. The Examiner concedes that Rubin does not disclose that the FRP protein is from human osteoblast cells (claim 2).

The Examiner relies on Chan for its teachings of a mammalian homolog, *i.e.*, the rat homolog of the *Drosophila frizzled (fz)* gene, which is described as being widely expressed in mammalian tissues. The Examiner states that Chan teaches that the hormonal induction of Fz proteins in osteoblasts serves to promote intracellular signaling required for function responses such as increased bone resorption (citing the Abstract).

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to combine the teachings of Rubin with those of Chan to use an FRP protein isolated from human osteoblast cells for generating a pharmaceutical composition comprising an antibody against sFRP-1, wherein the sFRP-1 protein is from human osteoblast cells. The Examiner concludes that one of ordinary skill in the art would have been motivated to make such an antibody because Rubin teaches that an anti-RFP antibody can be used in a pharmaceutical composition, and Chan teaches that mammalian tissues, *i.e.* rat osteoblasts, contain such proteins. (*See*, Office Action, page 7-8).

The Examiner relies on Chan for teaching FRP from human osteoblast cells. However, Chan describes rat Fz-1 and Fz-2 proteins and provides comparisons with the *Drosophila* protein and merely hypothesizes about the general nature of mammalian Fz proteins. Chan provides no teaching with respect to a human protein of SEQ ID NO:2 from human osteoblast cells. Thus, the Examiner's reliance on Chan is misplaced and the combination of Rubin and Chan do not teach or suggest each and every limitation of the claimed invention.

Furthermore, as discussed herein, claim 1 has been amended to recite “an antibody generated using a secreted frizzled related protein-1 (sFRP-1) of SEQ ID NO:2 as an immunogen,

wherein the antibody promotes bone-forming activity in a mammal.” Dependent claim 2 further specifies that the sFRP-1 is from human osteoblast cells. Nothing in Rubin or Chan provides a teaching or motivation, much less the expectation of success for making the claimed pharmaceutical composition comprising an antibody with the property of promoting bone-forming activity in a mammal.

For a claim to be obvious under U.S. patent law, the Examiner must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. Additionally, the Patent Office must articulate the reason(s) why a skilled artisan “would have recognized” that the results of the prior art “were predictable” (*see* Examination Guidelines, Department of Commerce, *Federal Register*, 72(195):57529 (October 10, 2007). Nothing in Rubin’s general teaching regarding an anti-RFP antibody and Chan’s description of rat Fz-1 and Fz-2 proteins would lead one of ordinary skill in the art to the claimed pharmaceutical compositions.

Therefore, reconsideration of claim 2 and withdrawal of the rejection of this claim under 35 U.S.C. § 103(a) is requested.

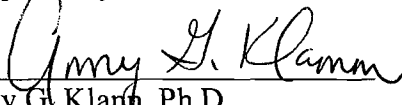
CONCLUSION

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. Applicants reserve the right to pursue the cancelled and/or non-elected subject matter in one or more continuation or divisional applications.

If there are any other issues remaining, which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

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Respectfully submitted,

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